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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/825,309
Filing Date: April 16, 2004
Appellant(s): KUSLEIKA, RICHARD S.

Richard S. Kusleika
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/02/09 appealing from the Final Office action mailed 03/05/09.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,994,033	Shockey et al.	2-1991
5,447,497	Sogard et al.	9-1995
5,413,822	Rey	5-1995
3,651,591	Woodyard	3-1972
5,611,775	Machold et al.	3-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-24, 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shockey et al. (US 4,994,033) in view of Sogard et al. (US 5,447,497).

Regarding claims 16-18, Shockey discloses a process for treating tissue at a treatment site within a body lumen, comprising: providing an elongate flexible catheter 12 having a flexible treatment sheath 22 mounted to a distal end region of the catheter and a dilatation balloon 30 within the flexible treatment sheath, wherein the flexible treatment sheath is formed of a elastic material;

intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a treatment site (col. 3, lines 55-66); supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, cause the treatment fluid to pass through the treatment sheath (through the holes 28) to the surrounding tissue, and maintain the treatment sheath expanded into the contact (col. 3, line 55-col. 4, line 8); at this point, the treatment sheath 22 is expanded because the drug or other material is introduced; the treatment sheath 22 having holes 28, therefore, it is inherently that some of drug or other material introduced into the lumen of treatment sheath will exit out through the holes 28 and delivery to target sites. At this times, the dilatation balloon 30 stills in unexpanded condition;

while maintaining the treatment sheath in the substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon 30 within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue (col. 4, lines 8-29). It is well-known in the art to performing step in claims 17-18.

Shockey does not disclose the dilation balloon 30 is formed of a substantially inelastic materials.

Sogard discloses a similarly device comprising an elongate flexible catheter 20 having a flexible treatment sheath (outer sheath) 26 mounted to a distal end region of the catheter and a dilatation balloon (inner balloon) 28 within the flexible treatment sheath 26, wherein the flexible treatment sheath 26 is formed of an elastic member, such as high-compliant balloon are made from soft or flexible polymeric materials (col. 2, lines 28-40, col. 8, lines 30-31); and the dilatation/inner balloon 28 is non-compliant balloon are made from inelastic materials such as rigid or stiff polymeric materials (col. 2, lines 43-52, col. 8, lines 49-50).

As noted that Applicant acknowledge that the inelastic materials such as PET, polypropylene (see page 2 of Pre-Appeal Brief filed 7/28/08) are similar to materials that Sogard discussed in col. 2, lines 43-52, col. 8, lines 49-50.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Shockey with a dilatation balloon made of an inelastic material, as taught by Sogard, in order to dilate and prevent the rupture of balloon since the small increase in diameter when the balloon inflated to its expanded diameter

Regarding claim 19, a guide wire 18 with a distal end thereof outside of the body, inserting the proximal end of the guide wire lumen running through the catheter, and advancing the catheter distally relative to the guide wire.

Regarding claims 20-21, the supplying of the treatment fluid comprises causing the treatment fluid to perfuse through the pores 28 in the treatment sheath.

Regarding claims 22-24, the dilatation balloon 30 radially enlargeable by supplying a dilatation fluid to a dilatation chamber formed by the balloon and the catheter, wherein the contraction of the dilatation balloon comprise withdrawing the dilatation fluid from the dilatation chamber to substantially evacuate the dilatation balloon (col. 4, lines10-30); allowing the treatment sheath to radially contract comprise withdrawing the treatment fluid from the compartment through the pores 28; allowing a flow of body fluids through the catheter past the treatment site (col. 4, lines 15-23).

Regarding claim 38, the treatment sheath 22 is formed of a biocompatible elastomeric material such as a thermoplastic elastomer includes polyethylene tetrathalate or polyvinyl chloride (col. 3, lines 12-16). Furthermore, it is well-known in the balloon art to made of materials in claim 38.

Regarding claim 39, Shockey in view of Sogard fail to disclose that the biocompatible elastomeric material has a modulus of electricity in range of 2,000 to 80,000 psi; the sheath has a thickness in the range of 0.5-5 mils. It would have been obvious to one having ordinary skill in the art at the time of the invention was made to provide the values list in claim 39, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

(10) Response to Argument

Group I (Claims 16, 19-21 and 24)

1. Applicant argues that the outer expander member 22 of Shockey is substantially inelastic.

In response, Shockey discloses the outer expander member 22 made of thermosetting plastic material such as polyethylene tetrathalate or polyvinyl chloride, see col. 3, lines 12-15. It is very well-known in the art that polyethylene tetrathalate or polyvinyl chloride is soft or elastic materials.

Evidences to show that polyethylene tetrathalate or polyvinyl chloride are elastic materials.

a) Sogard discloses that high-compliant balloons are made from soft or flexible polymeric materials. Examples of these materials are thermoplastic polymers, thermoplastic elastomers, polyethylene (high density, low density, intermediate density, linear low density), polyvinyl chloride, col. 2, lines 28-35. As noted that, the materials of the outer expander member such as the polyethylene and polyvinyl chloride are listed in to primary Shockey.

b) Applicant admitted that delivery sheath (flexible treatment sheath) 22 formed of an elastic biocompatible polymer, e.g, latex. Other suitable materials include polyurethane, silicon, and thermoplastic elastomers, see para [0047] of the Specification.

According to MPEP, the secondary reference can be provided to show that a characteristic not disclosed in the reference is inherent. (See below).

2131.01 Multiple Reference 35 U.S.C. 102 Rejections

Normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure;"
(B) Explain the meaning of a term used in the primary reference; or
(C) Show that a characteristic not disclosed in the reference is inherent.

See paragraphs I-III below for more explanation of each circumstance.

I. TO PROVE REFERENCE CONTAINS AN "ENABLED DISCLOSURE"

Extra References and Extrinsic Evidence Can Be Used To Show the Primary Reference Contains an "Enabled Disclosure"

When the claimed composition or machine is disclosed identically by the reference, an additional reference may be relied on to show that the primary reference has an "enabled disclosure." *In re Samour,* 571 F.2d 559, 197 USPQ 1 (CCPA 1978) and *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (Compound claims were rejected under 35 U.S.C. 102(b) over a publication in view of two patents. The publication disclosed the claimed compound structure while the patents taught methods of making compounds of that general class. The applicant argued that there was no motivation to combine the references because no utility was previously known for the compound and that the 35 U.S.C. 102 rejection over multiple references was improper. The court held that the publication taught all the elements of the claim and thus motivation to combine was not required. The patents were only submitted as evidence of what was in the public's possession before applicant's invention.).

III. TO SHOW THAT A CHARACTERISTIC NOT DISCLOSED IN THE REFERENCE IS INHERENT

Extra Reference or Evidence Can Be Used To Show an Inherent Characteristic of the Thing Taught by the Primary Reference

"To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (The court went on to explain that "this modest flexibility in the rule that anticipation' requires that every element of the claims appear in a single reference accommodates situations in which the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." 948 F.2d at 1268, 20 USPQ at 1749-50.). Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). See MPEP § 2112 - § 2112.02 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.

Therefore, Examiner provides few references to show that the thermoplastic elastomers such as: polyvinyl chloride.

Rey (US 5,413,822) discloses in col. 2, lines 57-59 that:

The part 21 of said bracelet comprises a base 22 formed by a thermoplastic elastomer, for example of polyvinyl chloride or of polyurethane. On the outer surface 24 of such base 22 is provided a decoration 25 comprising a first layer 26 formed by a flexible thermofusible material. On the outer surface 28 of this first

Woodyard (US 3,651,591) discloses in col. 2, lines 3-5 that:

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and 13 are fixed to opposite faces of the backing sheet 12. Preferably the backing sheet is of material having a matte finish. Each of the three sheets may be composed of a flexible synthetic resin, which preferably is a thermoplastic elastomer, such as a suitable polyvinyl chloride resin, so that the sheets

From the evidences above, Shockey discloses the flexible treatment sheath (outer expander member) 22 is formed of an elastic material.

2. Applicant argues that Shockey device is designed for, and used for, simultaneous delivery of a drug and dilatation of a vessel. While the Applicant's invention, in which the treatment sheath is first expanded into a substantially conforming contact with the tissue to deliver the treatment fluid while maintaining dilatation in an unexpanded condition. Applicant further argues that Shockey states in col. 2, lines 3-7: [An] object of the invention is to provide a dilatation catheter in which the stenotic lesion being treated can be spread and expanded at the same time that it is sprayed with a plaque reducing drug or substance which forms a stent in situ. See page 11 of Appeal Brief filed 12/02/09.

In response, Shockey states in col. 2, lines 3-7 that a dilatation catheter in which the stenotic lesion being treated **can be** spread and expanded at the same time. The term "**can be**" is understood that it is possible applied in the procedure. Shockey clearly discloses the process for treating tissue at a treatment site such as the steps of delivery of drug and dilatation of a vessel are not at the same time. It is providing one step follows after another step as follows:

Claim 16	Shockey
- providing an elongate flexible catheter 18 having a flexible treatment sheath 22 mounted to a distal	- providing an elongate flexible catheter 12 having a flexible treatment sheath 22 mounted to a distal

end region of the catheter 18 and a dilatation balloon 24 within the flexible treatment sheath 22, wherein the flexible treatment sheath 22 is formed of a elastic material;	end region of the catheter and a dilatation balloon 30 within the flexible treatment sheath, wherein the flexible treatment sheath is formed of a elastic material;
- intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a treatment site;	- intraluminally advancing the elongate flexible catheter until the flexible treatment sheath is adjacent a treatment site. For example: the distal end of the innermost tube 16 is fitted over the proximal end of the guide wire and then advanced along the guide wire until the expander members 22 and 30 are juxtaposed with the lesion to be treated (col. 3, lines 55-66). At this point, the expander member 22 (flexible treatment sheath) and 30 (dilatation balloon) still in an unexpanded condition.
- while maintaining the dilatation balloon in an unexpanded condition, supplying a treatment fluid under pressure to a compartment formed by the treatment sheath, to elastically expand the treatment sheath radially into a substantially conforming contact with the surrounding tissue at the treatment site, case the treatment fluid to pass through the treatment sheath from the compartment to the surrounding tissue, and maintain the treatment sheath expanded into said contact;	- Once the distal end of the catheter is appropriately positioned, the selected drugs or other material is introduced through the proximal port 40 and through the lumen 32 and into the confines of the outer expander member (flexible treatment sheath) 22. The injection of the drug will cause some enlargement of the outer expander member (flexible treatment sheath) 22 but typically the pressure at which the drug material is injected is below the point where substantial amounts of the drug are ejected out through the micropores 28.

	See col. 3, line 67-col. 4, lines 8. At this point, the outer balloon member (flexible treatment sheath) 22 is partially expanded and contact with the surrounding tissue at the treatment site, the treatment sheath 22 having holes 28, therefore, it is inherently that some of drug or other material introduced into the lumen of treatment sheath will exit out through the holes 28 and delivery to target sites. At this times, the dilatation balloon 30 stills in unexpanded condition.
- while maintaining the treatment sheath in the substantially conforming contact with the surrounding tissue at the treatment site, radially expanding the dilatation balloon 24 within the compartment, whereby the dilatation balloon acts radially upon the surrounding tissue through the treatment sheath to effect a dilatation of the surrounding tissue.	- Shockey further discloses in col. 4, lines 8-24 that: to perform the substance delivery and dilatation, an inflation fluid is next injected through the port 42 and through the lumen 34 into the interior of the expander sleeve (dilatation balloon) 30. As pressure increased, typically 7-10atm, the expander member inflates to its predetermined maximum diameter and, in doing so, forces the liquid substance through the port 28 to effectively spray the lesion being treated with a particular drug or other material. The expansion of the inner sleeve/dilatation balloon 30 also results in pressure being exerted against the lesion, forcing it again the vessel wall as the drug or other substance is delivered.

3. Applicant further argues that the outer treatment sheath 22 of Shockey is not expanded into substantially conforming contact with the surrounding tissue while maintaining the dilatation balloon in an unexpanded condition. Page 12 of Appeal Brief filed in 12/02/09.

In response, the word "substantially" is very broad. Therefore, Examiner interprets very broadly that the outer treatment sheath 22 is almost or nearly contact with the surrounding tissue. Shockey states that: the expander member 22, 30 are juxtaposed with the lesion to be treated, col. 3, lines 58-62. As noted that, the vessel is very small, not only that, the lesion formed on the vessel will cause the channel of vessel narrower. When the catheter inserted into the vessel and the injection of the drug is introduced through the port 40, the injection of the drug will cause some enlargement of the outer treatment sheath 22. Therefore, one skill in the art would recognize that the outer treatment sheath substantial contact the lesion or target tissue. Again, at this point, the only outer treatment sheath 22 is partial expanded, but the dilatation balloon (inner balloon 30) is still in unexpanded condition.

4. Applicant argues that Sogard reference does not provide any suggestion or reason for modifying the Shockey procedure such that Shockey's outer sleeve 22 is expanded "into a substantially conforming contact with the surrounding tissue at the treatment site" prior to expansion of the inner sleeve 30.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this case, as discussed above, the step of outer sleeve is expanded into a substantially conforming contact with the surrounding tissue at the treatment site prior to expansion of the inner sleeve 30 is fully disclosed by Shockey's device. The only different between the claimed invention and the Shockey's device is that dilatation balloon (inner sleeve) 30 is not formed of a substantially inelastic material. Meanwhile, Sogard suggests the benefit of providing a dilatation balloon (inner balloon) formed of substantially inelastic material (non-compliant material) to easy for dilatation balloon, prevent rupture of balloon and function to crack the rigid calcified lesion, col. 2, lines 64-68. Therefore, one skill in the art would

recognize that modifying of dilatation (inner) balloon formed of inelastic material, as taught by Sogard, for the benefit of more controlling in dilatation to avoid rupture of the balloon and enhancing function of crack the rigid calcified lesion.

Group II (claims 17-18, 22-23)

Applicant argues that nothing in Shockey or Sogard suggests maintaining Shockey's outer expander in contact with tissue and delivering treatment fluid after the inner member is contracted.

In response, the step of maintaining the outer expander in contact with tissue and delivering treatment fluid after the inner member is contracted is very well-known in the art. As applicant aware that, Applicant did not argue the limitation above in the previous argument nor Pre-Appeal Brief Request For Review filed in 07/28/08. However, to prove this step above is well-known in the art, at this point, Examiner would like to provide extra reference which can be used to support the primary reference contains an "enabled disclosure". Also see MPEP under §2131.01 (To Prove Reference Contains An "Enabled Disclosure" Section.

Machold et al. (US 5,611,775) discloses similarly to the method of treating tissue. For example: the inner inflatable member 16, expanding the outer inflatable member 19. The expansion continues until the stenoisis is dilated. Upon completion of the dilation, the inner inflatable member 16 is then deflated. The outer inflatable member in contact with tissue and delivering treatment fluid, see Figs. 4-5 or col. 3, lines 39-58 or col. 5, lines 56-60. The Machold reference has been used by itself and evidence of the well-known step of maintaining outer expander in contact with tissue and delivering treatment fluid, and then contracting/deflated the inner balloon.

Group III (claims 38-39)

Applicant argues that claim 38 recites that the treatment sheath is formed of a biocompatible elastomeric material consisting essentially of at least one of the following: latex, urethane, silicone, and a thermoplastic elastomer. Only materials that Shockey discloses for its outer expander member 22 are the

inelastic materials polyethylene tetrathalate (PET) and polyvinyl chloride (PVC). (Page 16 of Appeal Brief filed on 12/02/09).

In response, as discussed under Group I (claims 16, 19, 20-21 and 24) above, Examiner clearly points out and also provides evidences to show that polyethylene tetrathalate or polyvinyl chloride are elastic materials. (Emphasis added).

Conclusion:

For the above reasons, it is believed that the rejections under 35 U.S.C are proper and should therefore be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Quynh-Nhu H. Vu

/Quynh-Nhu H. Vu/

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